REMARKS/ARGUMENTS

The art related rejections are withdrawn except for the rejection of claims 4 and 5 as being unpatentable over a combination of three references: Ogletree in view of Bernat (US 5,989,578) and further in view of Koike et al. (US-5,288,726).

The earlier rejection applied Ogletree and Koike. Bernat is now added to show a pharmaceutical composition of an ADP receptor blocking antiplatelet drug (e.g. clopidogrel or ticlopidogrel) in combination with aspirin. In view thereof, there is annexed hereto a DECLARATION by Atsuhiro SUGIDACHI which provides evidence of a synergistic effect when compound A and aspirin are used together as compared to when clopidogrel and aspirin are used together. This would not be expected by persons of ordinary skill in the art based on the cited references. Thus, the combination of Ogletree with Bernat further in view of Koike et al. cannot render the claims obvious.

The remaining rejections are (1) that the limitation "there is no thromboxane A2 receptor antagonist" is new matter (35 USC

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132 rejection of claims) and (2) fails to be supported by written description in the specification (35 USC 112 rejection of the claims).

Concerning claim 15 and the claims depending thereon, it is noted that claim 15 does not use the objected to language. Rather, claim 15 specifically excludes all components that would effect the essential characteristics of the claimed composition by use of the terminology "consisting essentially of". Therefore, the Examiner's reasons for the 35 USC 112 and 35 USC 132 rejections do not apply to claim 15 and claims dependent thereon. If the rejection is to be maintained, an explanation is requested so that a more specific response can be made.

As to the rejection itself, the first paragraph of 35 U.S.C. 112 requires that the "specification shall contain a written description of the invention...." The written description requirement has several policy objectives. "[T]he 'essential goal' of the description of the invention requirement is to clearly convey the information that an applicant has invented the subject matter which is claimed." *In re Barker*, 559 F.2d 588, 592 n.4, 194 USPQ 470, 473 n.4 (CCPA 1977). Another objective is to put the public in possession of what the applicant claims as

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the invention. See *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566, 43 USPQ2d 1398, 1404 (Fed. Cir. 1997), cert. denied, 523 U.S. 1089 (1998). The written description requirement of the Patent Act promotes the progress of the useful arts by ensuring that patentees adequately describe their inventions in their patent specifications in exchange for the right to exclude others from practicing the invention for the duration of the patent's term.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116. In this case, where a pharmaceutical composition is being claimed, the pharmaceutical arts are relevant.

An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed

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invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

"Compliance with the written description requirement is essentially a fact-based inquiry that will 'necessarily vary depending on the nature of the invention claimed.'" *Enzo Biochem*, 323 F.3d at 963, 63 USPQ2d at 1613. An application specification may show actual reduction to practice by describing testing of the claimed invention or, in the case of biological materials, by specifically describing a deposit made in accordance with 37 CFR 1.801 et seq. See *Enzo Biochem*, 323 F.3d at 965, 63 USPQ2d at 1614.

As is the present case, the issue often arises in the context of determining whether new or amended claims are supported by the description of the invention in the application as filed (see, e.g., *In re Wright*, 866 F.2d 422, 9 USPQ2d 1649 (Fed. Cir. 1989)). Compliance with the written description requirement is a question of fact which must be resolved on a case-by-case basis. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116 (Fed. Cir. 1991).

The present application, as originally filed, clearly supports the claims and that applicant was in possession of the invention when the application was filed. Support for the new claims and for the amended claims can be found in the original

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claims as well as in the specification. The specification describes the invention in the pharmaceutical formulations described therein. Especially in view of the nature of pharmaceutical compositions and the strong controls over what they may contain, a person skilled in the art does not expect pharmaceutical formulations to contain unnamed ingredients and especially unnamed ingredients that affect the essential properties of the composition. The exemplified formulations contain no other active ingredients e.g. shown on page 9 (including no thromboxane A_2 receptor antagonist). This alone conveys to a person of ordinary skill in the art the nature of the invention and supports excluding other components that affect the properties of the composition.

Furthermore, one should not only look at the Examples, but also the discussion of the invention in the specification. In this context, it is noted that the discussion in the last paragraph on page 4 describes the invention as a combination of two components and their effect. Similarly, in the discussion of other components of the composition starting near the end of page 5 and through the beginning of page 6, no other active agents are included, only the pharmaceutically acceptable excipients.

The specification therefore provides written support for the presently claimed invention and discloses the invention in such a

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way that the new or amended claims clearly do not contain new matter.

Finally, with respect to the anticipation rejection avoided with the proviso specifically excluding the thromboxane A_2 receptor antagonist, in addition to the support noted above, it is submitted that applicants can claim less of their invention than they originally disclosed and claimed even if there is no *ipsis verbis* support therefore (see *In re Wertheim*, 191 USPQ 90 (CCPA 1976); also *Union Oil* vs. *Atlantic Richfield*, 54 USPQ 1227, 1235 (CAFC 2000)).

In view of the above, it is submitted that the present invention as now claimed is fully supported by the original specification and is not shown or suggested by the art. Withdrawal of the rejections and allowance of the application are respectfully requested.

Respectfully submitted,

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Enclosure: Executed DECLARATION UNDER 37 CFR 1.132 (with one page attachment) of Atsuhiro SUGIDACHI dated April 27, 2006

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